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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,792	06/13/2001	Yonghong Xiao	02973.00035	3733

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EXAMINER	
RAMIREZ, DELIA M	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/879,792	XIAO ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,22-24,27,62-64 and 69-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,9-11,14,15,22,24,27,62-64 and 69-71* is/are rejected.

7)☒ Claim(s) *2,3,7,8,12,13 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Application

Claims 1-15, 22-24, 27, 62-64, 69-71 are pending.

Applicant's amendment of claims 1, 6, 11, 22, 27, 62, 69 and cancellation of claims 16-21, 25-26, 28-61, 65-78, 72-73 in Paper No. 10, filed on 12/10/2002 is acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Drawings

1. The drawings submitted on 12/10/2002 have been reviewed and are objected under 37 CFR 1.84 or 1.152. See attached Notice of Draftsperson's Patent Drawing Review. Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDOMENT of the application. In addition, if amendments to the specification are needed due to drawing corrections, Applicant is requested to submit such amendments while the case is being prosecuted to expedite the processing of the application.

Priority

2. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to provisional application No. 60/211224 filed on 6/13/2000, 60/283353 filed on 4/13/2001 and 60/283648 filed on 4/16/2001. It is noted however that it appears that SEQ ID NO: 11 and SEQ ID NO: 12 were first disclosed in provisional application No. 60/283353 filed on 4/13/2001.

Specification

3. The specification is objected to due to the presence of blank spaces. See page 89, line 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 27, 69-71 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. This rejection has been discussed at length in Paper No. 9, mailed on 9/10/2002.

7. Applicants argue that the term "stringent conditions" does not render the claims indefinite since according to Applicants, the specification in page 14, line 22-page 15, line 4 discloses the meaning of the term "stringent conditions". Therefore, Applicants assert that one of skill in the art would understand the bounds of the term as recited in the claims.

8. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. The specification discloses that typically for stringent conditions, a combination of temperature and salt concentration should be chosen that is approximately 12-20 °C below the Tm calculated using the equation of Bolton and McCarthy. However, as indicated in previous Office Action Paper No. 9, the specification also discloses in page 15, lines 3-5 that there is more than one stringent condition and discloses at least two substantially different wash conditions: 4X SSC at 65 C for stringent conditions and 0.2X SSC at 65 C for highly stringent

conditions. Therefore, it is unclear as to which polynucleotides are being claimed since these wash conditions will result in different polynucleotides being hybridized to the polynucleotides recited in the claims. For examination purposes, the term will be interpreted as "any hybridization condition". Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 27, 69-71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. This rejection has been discussed at length in Paper No. 9, mailed on 9/10/2002.

12. Applicants argue that claims 27 and 69 have been amended to the extent that they meet the written description requirement. In particular, claim 27 now recites "comprise at least 225 contiguous nucleotides of (a) the complete complement of the polynucleotide of SEQ ID NO: 11, (b) the complete complement of the cDNA insert of plasmid pCRII-TMSP3, (c) a polynucleotide which hybridizes under stringent conditions to (a) or (b), and (d) a polynucleotide which is degenerate variant of (a) or (c)". In regard to claim 69, Applicants argue that each of the molecules recited in the claim are adequately described. Applicants assert that the term "stringent conditions" was well known in the art when the application was filed and that the

specification describes the term, therefore, one of skill in the art can reasonably conclude that Applicants were in possession of polynucleotides which hybridize under stringent conditions to the polynucleotides recited in claims 27 and 69.

13. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. Claim 27 is still directed to a genus of polynucleotides of any function. As indicated above in claim rejections under 35 USC 112, second paragraph, claim 27 is still directed to a genus of polynucleotides of any function comprising at least 225 nucleotides of a polynucleotide which can hybridize under any condition to the complete complement of the polynucleotide of SEQ ID NO: 11 or the complete complement of the cDNA insert of plasmid pCRII-TMSP3. Similarly, claim 69 is still directed to a genus of polynucleotides of any function which can hybridize under any condition to the complete complement of the polynucleotide of SEQ ID NO: 11 or the complete complement of the cDNA insert of plasmid pCRII-TMSP3. As indicated in previous Office Action Paper No. 9, while there is disclosure of the function of the polynucleotide of SEQ ID NO: 11, there is no disclosure of other functions the claimed polynucleotides may have. Furthermore, there is no disclosure of the critical structural elements a (1) polynucleotide which hybridizes under any condition with the polynucleotide of SEQ ID NO: 11 or the cDNA insert of plasmid pCRII-TMSP3, or (2) a polynucleotide which comprises 225 nucleotides of the polynucleotides of SEQ ID NO: 11 or the cDNA insert of plasmid pCRII-TMSP3 should have to encode a protein with serine protease activity. In addition, there is no disclosure of which 225 nucleotides should be comprised by the claimed polynucleotides and still retain the function of the polynucleotide of SEQ ID NO: 11. It is noted that as written, the polynucleotides of claim 27 may contain none of the nucleotides of the complete complement of

the polynucleotide of SEQ ID NO: 11 or the cDNA insert of plasmid pCRII-TMSP3 since the polynucleotide from where the 225 nucleotides are obtained are polynucleotides which may have other nucleotides unrelated to the complete complements of the polynucleotides of SEQ ID NO: 11 or the cDNA insert, as implied by the term "comprising". For the reasons discussed above, one of skill in the art cannot reasonably conclude that the claimed invention is adequately described.

14. Claims 27, 69-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide of SEQ ID NO: 11 or a polynucleotide encoding the polypeptide of SEQ ID NO: 12, does not reasonably provide enablement for (1) polynucleotides of any function comprising 225 nucleotides of a polynucleotide comprising the nucleic acid of SEQ ID NO: 11 or the cDNA insert of plasmid pCRII-TMSP3, or any polynucleotide which hybridize under any condition to the polynucleotides above, or (2) polynucleotides of any function which can hybridize to the polynucleotide of SEQ ID NO: 11 or the cDNA insert of plasmid pCRII-TMSP3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

15. This rejection has been discussed at length in Paper No. 9, mailed on 9/10/2002.

16. Applicants argue that it would not require undue experimentation to make and use a polynucleotide comprising at least 225 nucleotides of a polynucleotide comprising the complete complement of the polynucleotide of SEQ ID NO: 11 or the complete complement of the cDNA insert of plasmid pCRII-TMSP3. In addition, Applicants argue that since the specification

defines the term "stringent hybridization conditions", a (1) polynucleotide comprising at least 225 nucleotides of a polynucleotide which hybridizes to the complete complement of the polynucleotide of SEQ ID NO: 11 or the cDNA insert of plasmid pCRII-TMSP3, or (2) polynucleotide which hybridizes to the polynucleotide of SEQ ID NO: 11 or the cDNA insert of plasmid pCRII-TMSP3 are enabled.

17. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. While it is agreed that making a nucleic acid molecule comprising at least 225 nucleotides as encompassed by the claims is not undue experimentation since base-pairing and the degeneracy of the genetic code is well known in the art, one of skill in the art would have to go through the burden of undue experimentation to determine how to use such polynucleotides. Claim 27 and 69 are directed to polynucleotides of any function. See discussion above. As such, one of skill in the art would have to determine their function to be able to use the invention. While the specification discloses the function of the polynucleotide of SEQ ID NO: 11 and that of the cDNA insert in plasmid pCRII-TMSP3, there is no disclosure of other functions associated with (1) polynucleotides which can hybridize under any condition to the polynucleotide of SEQ ID NO: 11 or the cDNA insert in plasmid pCRII-TMSP3, (2) polynucleotides comprising at least 225 nucleotides of the polynucleotides as recited by the claims, nor there is disclosure of which are the critical structural elements such polynucleotides should have to encode a human transmembrane serine protease, which is the only function disclosed in the specification. As indicated in previous Office Action Paper No. 10, the state of the art clearly teaches the unpredictability of assigning function based on sequence homology. See the teachings of Bork (Genome Research, 10:398-400, 2000), Van de Loo et al. (Proc. Natl.

Acad. Sci. 92:6743-6747, 1995) and Broun et al. (Science 282:1315-1317, 1998) previously discussed. In addition, as mentioned above, some of the polynucleotides encompassed by claim 27 may not have any of the nucleotides of the complete complement of the polynucleotide of SEQ ID NO: 11 or the cDNA insert of plasmid pCRII-TMSP3. As such, it is unclear as to how one of skill in the art can use the claimed polynucleotides at all since they won't even hybridize under any condition to the polynucleotide of SEQ ID NO: 11 or the cDNA insert of plasmid pCRII-TMSP3. Therefore, for the reasons set forth above, one cannot reasonably conclude that the enablement provided is commensurate with the scope of the claims.

18. Claims 62-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition containing an expression vector comprising the polynucleotide of SEQ ID NO: 11 or a polynucleotide encoding the polypeptide of SEQ ID NO: 12, does not reasonably provide enablement for a pharmaceutical composition comprising said vectors as encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

19. This rejection has been discussed at length in Paper No. 9, mailed on 9/10/2002.

20. Applicants argue that the PTO has failed in establishing a prima facie case of non-enablement since the specification discloses two types of diseases: viral infection and neurodegenerative diseases which can be treated with the claimed pharmaceutical compositions. Furthermore, Applicants argue that the Office has not provided scientific evidence or reasoning as to why one cannot treat viral infections and neurodegenerative diseases as asserted in the

specification. In addition, Applicants assert that the specification provides therapeutic doses and teaches how to determine such doses. According to Applicants, the specification teaches numerous examples of pharmaceutically acceptable carriers and that it would not require undue experimentation to make a pharmaceutical composition as recited in the claims. Finally, Applicants argue that a therapeutic invention need not be refined to the point where clinical efficacy in patients can be demonstrated in order to be patentable.

21. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. While it is not argued that the specification discloses diseases which can be treated with the claimed pharmaceutical compositions, as indicated in previous Office Action Paper No. 9, the specification discloses that the claimed pharmaceutical compositions can be used to treat a large number of diseases (pages 46-52) such as conditions related to tumor cell invasion and metastasis, tumor angiogenesis, inflammation and cellular immunity, viral infections, neurodegenerative diseases, restenosis and atherosclerosis, and chronic obstructive pulmonary disease, without providing any evidence which would lead one of skill in the art to reasonably conclude that such composition can be used to treat all those diseases. It appears that the assertion that the claimed pharmaceutical composition can be used to treat this large number of diseases is based only on the suggestion that membrane-associated proteases participate in cell surface biological events therefore diseases associated with biological processes such as extracellular matrix degradation can be targeted by the claimed compositions. Even if one considers the list of neurodegenerative diseases alone (page 49, line 16-page 50, line 19) which the specification asserts can be treated with the claimed pharmaceutical composition, it is unclear as to how one of skill in the art can reasonably conclude that the claimed composition can treat

diverse conditions such as Genstmann-Straussler Syndrome, Creutzfeldt-Jakob disease, Scrapie, Parkinson's disease, multiple sclerosis, Alzheimer's disease, Pick's disease, Huntington's disease, HIV dementia, schizophrenia with dementia, etc., without a single piece of experimental evidence or prior art suggestion to that effect. There is no evidence and/or data provided for any of the conditions listed. In regard to therapeutical doses, it is noted that the dosage range provided is so broad (0.1 μg to 1 g), that finding the appropriate dosage for each of the diseases listed would constitute undue experimentation. While the Examiner agrees that mixing the components of a pharmaceutical composition to obtain different combinations of pharmaceutical carriers and the active ingredient is not undue experimentation, determining which combination is appropriate for the condition being treated in humans is not routine in the art. It is noted that this rejection is not applied due to lack of clinical efficacy data, as asserted by Applicants, but rather due to the complete lack of any evidence or suggestion which would lead one of skill in the art to reasonably conclude that the composition can have the pharmaceutical uses as asserted and the lack of information as to which dosages are appropriate for the conditions recited.

22. Claims 1, 4-6, 9-11, 14-15, 22, 24, 27, 62, 64, 69-71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel vectors. Since the vectors are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmids sequences are not fully

disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the plasmids. Since the specification does not disclose a repeatable process to obtain the vectors and it is not apparent if the DNA sequences are readily available to the public, it is deemed that a deposit of these plasmids should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that applicants have deposited the plasmid but there is no indication in the specification or in the Response filed on 12/10/2002 as to public availability. While Applicants have provided a copy of an International Form from ATCC where it is stated that the instant plasmid has been deposited, it is unclear from such form that the deposit will be irrevocably and without restriction or condition released to the public upon the issuance of the patent. In particular, the statement "or if a US Patent is issued citing the strain and ATCC is instructed by the USPTO or the depositor to release said strain" appears to indicate that even after issuing a US patent citing the instant plasmid, public availability can be restricted by the depositor (Applicants). It is noted that while the specification discloses that the plasmids were deposited under the terms of the Budapest Treaty, such terms do not refer to public availability. Therefore, Applicants need to submit an affidavit or declaration, or a statement by an attorney of record over his or her signature and registration number, stating that the specific vector has been deposited under the Budapest Treaty and that the vector will be irrevocably and without restriction or condition released to the public upon the issuance of the patent.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 27 and 69-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al. (GenBank accession number R78581, 1995; cited in the IDS).

24. This rejection has been discussed at length in Paper No. 9, mailed on 9/10/2022.

25. Applicants argue that the claims as amended are not anticipated by Hillier et al. since the polynucleotide of Hillier et al. does not encode the protein of SEQ ID NO: 12 or the protein encoded by the cDNA insert of plasmid pCRII-TMSP3. Furthermore, the polynucleotide of Hillier et al. does not contain at least 225 nucleotides of the complete complement of the polynucleotide of SEQ ID NO: 11 or the cDNA insert of plasmid pCRII-TMSP3.

26. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection as it relates to claims 27 and 69-71. While it is agreed that Hillier et al. does not teach the polynucleotide of SEQ ID NO: 11 or the cDNA insert of plasmid pCRII-TMSP3, the polynucleotide of Hillier et al., which comprises 151 contiguous nucleotides of SEQ ID NO: 11 can hybridize to a polynucleotide comprising the complete complement of SEQ ID NO: 11. Since claim 27 is drawn to a polynucleotide comprising at least 225 nucleotides of a polynucleotide which hybridizes to a nucleic acid comprising the complete complement of SEQ ID NO: 11, the polynucleotide of Hillier et al. anticipates the claim as written. Similarly, since claims 69-71 are drawn to any polynucleotide which hybridizes with the polynucleotide of SEQ ID NO: 11, a vector and a host cell comprising said polynucleotide, the polynucleotide, vector and host cells of Hillier et al. anticipate the claims as written.

27. Claims 27, 69-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Paolini-Giacobino et al. (Genomics 44:309-320, 1997; cited in the IDS).

28. This rejection has been discussed at length in Paper No. 9, mailed on 9/10/2022.

29. Applicants argue that the claims as amended are not anticipated by Paolini-Giacobino et al. since the polynucleotide of Paolini-Giacobino et al. does not encode the protein of SEQ ID NO: 12 or the protein encoded by the cDNA insert of plasmid pCRII-TMSP3. Furthermore, the polynucleotide of Paolini-Giacobino et al. encodes a protein which is only 24.6% sequence identical to the polypeptide of SEQ ID NO: 12.

30. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection as it applies to claims 27, 69-71. While it is agreed that the polynucleotide of Paolini-Giacobino et al. does not encode the protein of SEQ ID NO: 12 or the protein encoded by the cDNA insert of plasmid pCRII-TMSP3, the polynucleotide of Paolini-Giacobino et al. contains several fragments which are complementary to the polynucleotide of SEQ ID NO: 11, therefore the polynucleotide of Paolini-Giacobino et al. can hybridize to the polynucleotide of SEQ ID NO: 11. Since claim 27 is drawn to a polynucleotide comprising at least 225 nucleotides of a polynucleotide which hybridizes to a nucleic acid comprising the complete complement of SEQ ID NO: 11, the polynucleotide of Paolini-Giacobino et al. anticipates the claim as written. Similarly, since claims 69-71 are drawn to any polynucleotide which hybridizes with the polynucleotide of SEQ ID NO: 11, a vector and a host cell comprising said polynucleotide, the polynucleotide, vector and host cells of Paolini-Giacobino et al. anticipate the claims as written.

31. Claims 27, 69-71 are rejected under 35 U.S.C. 102(a) as being anticipated by Kim et al. (Biochim. Biophys. Acta 1518:204-209, March 19, 2001; SPTREMBL accession number Q9BYE2; GenBank accession number AB048796). Kim et al. teaches the cloning and expression of a mosaic human transmembrane serine protease, vectors and host cells comprising the DNA encoding such protease. The polynucleotide of Kim et al. comprises nucleotides 1-1672 of SEQ ID NO: 11 except for one mismatch. As such, the polynucleotide of Kim et al. can hybridize to the complete complement of the polynucleotide of SEQ ID NO: 11. The polypeptide of Kim et al. comprises residues 1-554 of SEQ ID NO: 12 except for one mismatch. See attached alignments. Since claim 27 is directed to a polynucleotide which comprises at least 225 nucleotides of (1) the complete complement of the polynucleotide of SEQ ID NO: 11 or (2) a polynucleotide which hybridizes under any condition to the polynucleotide of SEQ ID NO: 11, the polynucleotide of Kim et al. anticipate the claim as written. Similarly, since claims 69-71 are directed to any polynucleotide which hybridizes with the polynucleotide of SEQ ID NO: 11, a vector and a host cell comprising said polynucleotide, the polynucleotide, vector and host cell of Kim et al. anticipate the claims as written.

Claim Rejections - 35 USC § 103

32. Claim 22 was rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al. or Paolini-Giacobino et al.

33. This rejection is discussed at length in Paper No. 9, mailed on 9/10/2002.

34. In view of Applicant's amendment of claim 22, which is now directed to a method of producing the polypeptide of SEQ ID NO: 12 or the polypeptide encoded by the cDNA insert of plasmid pCRII-TMSP3, this rejection is hereby withdrawn.

Allowable Subject Matter

35. Claims 2-3, 7-8, 12-13, 23 appear to be allowable over the prior art of record but are objected to since they depend upon rejected claims.

Conclusion

36. No claim is in condition for allowance.

37. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

38. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
February 26, 2003

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1600~~ 1600